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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124495
Facility ID:201731
Inspection ID #2017310005

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-36

July 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Ashok K. Sharma, Radiologist
611 South Carlin Springs Road
Suite 410
Arlington, Virginia 22204

Dear Dr. Sharma:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on June 27, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

- **Your facility failed to document that phantom image testing was performed for at least 12 weeks in the 12 months prior to the date of your inspection.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **During two processing days, your facility processed mammograms when your mammography processor was out of limits;**
- **Corrective action was not documented at least once when your processor exceeded preset operating limits;**
- **Your facility failed to document that processor quality control was performed for one out of four operating days in the month of April 2001;**
- **Four of ten random mammography reports reviewed during your inspection failed to contain an acceptable assessment category.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 900 Madison Avenue, Baltimore, MD 21201, to the attention of Anita Richardson, Director, Compliance Branch.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Fred Gorisch, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
Main Street Station
1500 East Main, Room 240
Richmond, Virginia 23219

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091